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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/803,412	03/09/2001	Harry W. Schmidt	T268.12-0047	4806

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EXAMINER

CROSS, LATOYA I.

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 03/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/803,412

Applicant(s)

SCHMIDT ET AL.

Examiner

LaToya I. Cross

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 13 and 14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 March 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of group I, claims 1-11, 13 and 14 in the paper dated December 31, 2003 is acknowledged. Claim 12 is withdrawn from consideration as being non-elected.

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "568" has been used to designate the vial ejector tab, but reference character "568" does not appear to be pointing at the same part in figures 2 and 3. In figure 2, "568" is pointing to a structure below the boot (558). In figure 3, "568" is pointing to a structure extending from the boot (558). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claim 1 recites "A vial autosampler". As components of the autosampler,

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the claims recite a sampling module including a needle and a sealing boot disposed about the needle. The claims are indefinite because these structural components do not define "vial autosampler", but rather define a sampling module to be used in a vial autosampler. It is suggested that Applicants amend the preamble to "sampling module" or something similar or Applicants should amend the body of the claims to recite the additional components of a autosampler that Applicants state are typical at page 1, lines 22-28 of the specification (storage area to hold vials and a means for grasping and transporting vials).

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

6. Claims 1, 2, 9-11, 13 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 4,713,974 to Stone.

Stone teaches an autosampler comprising inter alia, a needle assembly. The needle assembly comprises a sampling needle (260) adapted to pierce the septum of a vial (77). The autosampler also comprises a vial stabilizer (320), equivalent to Applicants' claimed sealing boot, which engages the top of vial (77) as it is lifted toward needle (260). See col. 6, lines 22-27). As shown in figure 4, the vial stabilizer engages the vial septum when the vial is engaged with needle. With respect to claim 2, the arm (325), in conjunction with the vial stabilizer, serve as an ejector tab because when the arm (325) moved downward on the guide rod, the arm, in conjunction with the vial stabilizer, urge the vial away from the needle. With respect to claim 9, the vial stabilizer would inherently limit leakage between the needle and the septum

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because the needle would have to pass back through the stabilizer to exit completely. With respect to claim 10, figure 3 shows the vial stabilizer being disposed at a proximate end of the tip of the needle. With respect to claim 11, figures 4 and 8 show a needle housing (280), which has a structure at its lower end coupled to arm (300). This feature is equivalent to Applicant's claimed needle block because if the vial stabilizer, when lifted by a vial on the vial lifter, cannot move up the guide rod any further than this lower portion of the needle housing. Likewise, with respect to claim 14, where the vial stabilizer is lifted up to its maximum point (where the vial stabilizer contacts the lower portion of the needle housing), a seal is created between the needle housing, the vial and the vial stabilizer. With respect to claim 13, Stone teaches that the vial is lifted up toward the sampling needle (260) so as to bring the needle into contact with vial (77). Then, the vial stabilizer (320) engages the septum of the vial.

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be anticipated, within the meaning of 35 USC 102(b) in view of the teachings of Stone.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 3-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stone in view of US Patent 5,632,895 to Tsukagoshi et al.

The disclosure of Stone is described above. Stone fails to teach the material used for the vial stabilizer and the hardness of the material.

Tsukagoshi et al teach a blood collecting assembly whereby a blood sample is removed from a vial containing the sample using a syringe. Tsukagoshi et al teaches the importance of the material in the vial through which the needle moves with respect to the seal that exists at the mouth of the vial. Specifically, Tsukagoshi et al teach that the material at the mouth of the vial should be a rubber material, such as silicone rubber, having a hardness of 30-60.

Tsukagoshi et al explain that this material easily permits the penetration of the needle into the vial and allows resealing after the needle is removed to maintain the sealed environment.

It would have been obvious to one of ordinary skill in the art to use silicone rubber as the material for the vial stabilizer in Stone because the silicone rubber material would enhance the seal between the needle and the vial and thus prevent contamination of the vial contents.

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be obvious within the meaning of 35 USC 103 in view of the teachings of Stone and Tsukagoshi et al.

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Allowable Subject Matter

10. Claims 7 and 8 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.


Claims 7 and 8 recite a sealing boot having an upper and lower plate, a first gasket sealing between the upper plate and the ejector tab and second gasket sealing between the lower plate and ejector tab. The prior art of record fails to teach or suggest a sealing boot having an upper and lower plate and first and second gasket sealings.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is 571-272-1256. The examiner can normally be reached on Monday-Friday 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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March 17, 2004


Jill Warden
Supervisory Patent Examiner
Technology Center 1700